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<b>PRE-APPEAL BRIEF REQUEST FOR REVIEW</b>		Docket Number (Optional) 007404-000571									
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]  on _____  Signature _____  Typed or printed name _____	Application Number  10/692,031	Filed  October 23, 2003									
	First Named Inventor Crismore, William F.										
	Art Unit 1797	Examiner Alexander, Lyle									
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p>  <p>This request is being filed with a notice of appeal.</p>  <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p>  <p>I am the</p> <table style="width: 100%; border: none;"><tr><td style="width: 50%; vertical-align: top; padding: 5px;"><input type="checkbox"/> applicant/inventor.</td><td style="width: 50%; vertical-align: top; padding: 5px;">/Thomas Q. Henry, Reg. No. 28309/ Signature</td></tr><tr><td style="vertical-align: top; padding: 5px;"><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</td><td style="vertical-align: top; padding: 5px;">Thomas Q. Henry Typed or printed name</td></tr><tr><td style="vertical-align: top; padding: 5px;"><input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>28309</u></td><td style="vertical-align: top; padding: 5px;">(317) 634-3456 Telephone number</td></tr><tr><td style="vertical-align: top; padding: 5px;"><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</td><td style="vertical-align: top; padding: 5px;">July 9, 2009 Date</td></tr></table> <p style="margin-top: 10px;">NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p>				<input type="checkbox"/> applicant/inventor.	/Thomas Q. Henry, Reg. No. 28309/ Signature	<input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)	Thomas Q. Henry Typed or printed name	<input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>28309</u>	(317) 634-3456 Telephone number	<input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____	July 9, 2009 Date
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<input checked="" type="checkbox"/> *Total of <u>1</u> forms are submitted.											

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application No.: 10/692,031  
Confirmation No.: 5358  
First-Named Inventor: William F. Crismore  
Filing Date: October 23, 2003  
Group Art Unit: 1743  
Examiner: Alexander, Lyle  
Attorney Docket No.: 007404-000571  
Title: ELECTROCHEMICAL BIOSENSOR TEST STRIP

**REMARKS FOR PRE-APPEAL BRIEF REVIEW**

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

These Remarks for Pre-Appeal Brief Review are being filed along with a Pre-Appeal Brief Request for Review (PTO/SB/33) and Notice of Appeal (as well as associated fees). No Appeal Brief has yet been filed. A Petition for a One Month Extension of Time, and the accompanying fee, are also submitted herewith.

The Commissioner is authorized to charge any additional extensions of time as well as any additional fees or credit any overcharges to Deposit Account No. 23-3030, but not to include any payment of issue fees.

The latest Office Action in this case was mailed on March 9, 2009 (the "Latest Action"). This Latest Action does not indicate whether it is final or non-final. However, no claim amendments were made in applicant's most recent Response and Interview Summary filed on December 23, 2008 (the "December Response"). Therefore, the same pending claims have been twice rejected in office actions mailed on October 16, 2008 and March 9, 2009, and are ripe for appeal on that basis. 37 CFR 41.31. These Remarks are based on the claims as contained in the December Response.

***The Claims***

Claims 68-104 are pending, of which claims 68, 82 and 96 are independent. Each of the independent claims requires (1) "a solid, transparent or translucent viewing material", and (2) a

“fill line”. The supporting disclosure for these limitations has been cited in the Response to Final Office Action submitted on December 21, 2007 and in the Response and Interview Summary submitted on December 23, 2008. Exemplary portions of the disclosure include the following:

“The roof of the capillary test chamber includes a transparent or translucent window which operates as a ‘fill to here’ line, thereby identifying when enough test sample (a liquid sample, such as blood) has been added to the test chamber to accurately perform a test.” US Patent No. 5,997,817, Abstract, lines 11-15

“[I]t is possible for a user of reasonable visual acuity to determine if the window is entirely full of the sample. By choosing the window dimensions as just stated it is possible to provide feedback for the user of the test strip that the strip has been sufficiently dosed with a test sample. Visual confirmation of the window being full provides assurance that a sufficient area of the working electrode is covered with sample and that a sufficient part of the counter or reference electrode 6 is also covered.” US Patent No. 5,997,817, col. 8, line 63 to col. 9, line 4.

### ***The Claim Rejections***

All of the claims have been rejected under §102 as being anticipated by each of U.S. Patent Nos. 5,437,999 to Diebold et al. (“Diebold ‘999”), 5,942,102 to Hodges et al. (“Hodges ‘102”), 6,174,420 to Hodges et al. (“Hodges ‘420”), 5,798,031 to Charlton et al. (“Charlton ‘031”), 5,575,895 to Ikeda et al. (“Ikeda ‘895”), 5,264,103 to Yoshioka et al. (“Yoshioka ‘103”), 5,695,949 to Galen et al. (“Galen ‘949”), 6,027,692 to Galen et al. (“Galen ‘692”), 4,684,445 to Seshimoto et al. (“Seshimoto ‘445”), and 4,473,457 to Columbus (“Columbus ‘457”). Applicants submit, however, that these references fail to disclose a “solid, transparent or translucent viewing material” and a “fill line”.

### ***The “Fill Line” Limitation***

The Latest Action has rejected the claims under §112 based on the reference in the claims to a “fill line”. While this basis of rejection is probably not an issue to be addressed in the Pre-Appeal Review program, it requires a brief comment for purposes of dealing with the §102 rejections.

The Latest Action (page 2) argues that “The original specification . . . does not teach a ‘fill line’ to determine the proper amount of sample.” However, applicants have cited to supporting disclosure in the specification which states, *inter alia*, that “The roof of the capillary test chamber includes a transparent or translucent window which operates as a ***‘fill to here’ line***.

US Patent No. 5,997,817, Abstract, lines 11-15. The claim term is therefore clearly shown to be supported by the original disclosure, and it must be addressed in formulating a §102 or §103 rejection of the claims.

Applicants do intend to amend the claims to change the term to a “fill to here line” in order to remove any possible doubt as to §112 support. However, applicants also submit that the two terms (“fill line” and “fill to here line”) are equivalent and interchangeable, and that the slight wording difference is not a proper ground for rejecting the pending claims under §112.

***Basis for the Review Request - Missing Claim Elements***

All of the claims of the present application include the combination of a solid, transparent or translucent viewing material and a fill line. Each of the independent claims 68, 82 and 96 describes a capillary-fill, electrochemical test strip in which the movement of a blood sample to a fill line can be visualized through the solid, transparent or translucent material to provide confirmation to the user that sufficient blood has been dosed to the strip, and has reached the required test area, such that the test results can be accurate.

In contrast, all of the cited references have a common failing with respect to the present claims - a blood sample can not be viewed through a solid, transparent or translucent material as the sample fills a capillary channel inwardly from the edge of a test strip to a fill line:

- Diebold ‘999 includes a capillary channel defined by a cutout 49 sandwiched between top and bottom layers. There is no indication that either of the outer layers is transparent or translucent, or that there is any kind of fill line, and indeed the capillary channel is shown as being hidden (see dashed lines in Fig. 6) by the outer layers.
- Hodges ‘102 and ‘420 show sandwich-type test strips in which the interior, circular chamber is hidden by the outer layers and consequently there is no fill line.
- Charlton ‘031 shows a test strip having a base 36 and a lid 46, with the lid embossed to form a concave space 48 constituting the capillary channel. Charlton does not identify any solid portion(s) of the base or lid as being transparent or translucent, and does not identify a fill line.
- Ikeda ‘895 discloses a sandwich-type test strip with top and bottom layers 6 and 9 and an interior chamber 11-11b. There is no indication that any portion of the layers 6 or 9 is transparent or translucent, and there is no fill line.

- Yoshioka ‘103 has a similar sandwich-type design, and fails to show that any portion of the outer layers 1 or 4 is transparent or translucent or that there is a fill line.
- Galen et al. ‘949, and ‘692 disclose top-dosing strips with openings 6, 7 and 11 extending from a top substrate through to a bottom substrate. There is no solid, transparent or translucent portion to allow blood to be visualized as it fills a capillary channel, and no fill line to indicate when sufficient filling has occurred.
- Seshimoto ‘445 discloses a device including a bottom plate 21 and a top plate 18, with testing electrodes 11a-11c received in an interior passage 14. Sample is received at top opening 12 and then directed down through passage 13 to the interior 14. There is nothing in Seshimoto ‘445 to suggest that any part of plate 21 or plate 18 is transparent or translucent to allow viewing of the sample as it moves along interior passage 14, or that there is a fill line.
- Columbus ‘457 provides a device in which sample is received through a top opening 42 or 42’ and conveyed through a capillary channel defined by surfaces 34 and 36. There is no indication that the top 30 (including surface 34) or the bottom 32 (including surface 36) is transparent or translucent, or that there is a fill line.

By comparison, the present invention provides a uniquely advantageous design for a capillary-fill test strip in which the filling of the strip is viewable to show if adequate filling has occurred to conduct a test. Test strips which do not adequately fill can produce inaccurate results. The present invention provides an elegant solution to this problem by allowing the users to visually watch the blood fill the test strip, and to readily determine whether the blood makes it to the fill line – the indicator when at least enough blood has been added.

The Latest Action fails to address the claim limitations regarding the solid, transparent or translucent viewing material or the fill line. In citing to the prior art references, the action identifies a number of elements found in the claims - e.g., electrodes, capillary channel, reagent, etc. However, the action generally fails to identify anything in the cited patents considered to meet the limitation of a “solid, transparent or translucent viewing material.” In citing Seshimoto ‘445, Columbus ‘457 and Charlton ‘031 (erroneously referred to as Ikeda) at page 6, lines 2-6, the action suggests that the references include “transparent . . . portions.” However, the action fails to cite to any disclosure in these references to that effect, and applicants are unable to locate such a disclosure. Similarly, the action references the “contamination prevention layers” in

Galen ('949 or the divisional '692) and contends that they equate to the claimed transparent viewing material. However, there is no indication in the Galen patents as to whether such layers are transparent, translucent or opaque.

Regarding the “fill line” limitation, the office action fails to cite to anything in the prior art references that discloses this feature. Instead, the action indicates that if the fill line limitation is given weight, then “the Office would maintain it is notoriously well known in the analytical art to provide a fill line to let the user know if enough fluid sample has been added.” This does not satisfy the requirement of the Patent Office for showing anticipation or obviousness. If this limitation is indeed “notoriously well known”, then references must be identified for this proposition so that applicants can address the issue. Absent that, the rejections are inappropriate on their face.

### ***Conclusion***

It is respectfully requested that the bases for the rejections of the pending claims be reviewed. If there are any questions or comments that would speed the prosecution, the Office is requested to contact the undersigned by telephone.

Respectfully submitted,

July 9, 2009

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